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IN THE

Supreme Court of the United States

APOTEX CORP.,

Petitioner,

v.

MERCK & CO., INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

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QUESTION FOR REVIEW

Whether Petitioner Apotex has presented compelling reasons to grant the Petition, where the Federal Circuit affirmed the District Court's rejection of Apotex's independent action under Fed. R. Civ. P. 60(b) under the abuse of discretion standard of review, an approach consistent with the standard of review applied by the Federal Circuit and other circuits.

CORPORATE DISCLOSURE STATEMENT

No parent or publicly held company owns 10% or more of Respondent Merck & Co., Inc.'s stock.

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I. INTRODUCTION

Petitioner Apotex Corp. ("Apotex") wrongfully accused Respondent Merck & Co., Inc. ("Merck") and its attorneys of fraud on the court in an earlier patent litigation, during which two Apotex patents were held invalid.[1] In this litigation, Apotex sought relief from the earlier judgment through an independent action under Fed. R. Civ. P. 60(b) ("Rule 60(b)") in a suit brought in the Northern District of Illinois. The district court found that Apotex presented no evidence that Merck or its attorneys did anything improper in the earlier litigation, and entered summary judgment in Merck's favor.[2] Under the abuse of discretion standard of review that applies to Rule 60(b) actions, a unanimous panel of the Federal Circuit affirmed. Apotex's petition for rehearing and rehearing *en banc* was denied.

Merck respectfully urges this Court to deny Apotex's petition for writ of *certiorari* ("Petition"). First, Apotex's Petition is incorrectly premised upon a supposed split among the circuits about the appellate standard of review for Rule 60(b) independent actions. Yet the only

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[1] *Apotex USA, Inc. v. Merck & Co., Inc.*, 254 F.3d 1031 (Fed. Cir. 2001).

[2] The district court also denied Apotex's attempt to intrude into Merck's privileged information from the earlier litigation under the crime-fraud exception. *Apotex Corp. v. Merck & Co., Inc.*, 229 F.R.D. 142 (N.D.Ill 2005). The Federal Circuit panel unanimously affirmed, and Apotex's Petition does not seek review of that decision. As the Federal Circuit held, Apotex could not even establish a *prima facie* case of fraud. *Apotex Corp. v. Merck & Co., Inc.*, 507 F.3d 1357, 1362 (Fed. Cir. 2007).

evidence Apotex offers of this "split" is misapplication of a Third Circuit opinion, in which the court performed *de novo* review of the district court's dismissal of a case under Fed. R. Civ. P. 12(b)(6). Second, considering Apotex presented no evidence that Merck and its attorneys acted improperly in the earlier litigation, the Federal Circuit would also have been compelled to affirm under the *de novo* standard of review.

II. STATEMENT OF THE CASE

A. Merck Publicly Disclosed the Process Claimed by the Invalid Apotex Patents Before Apotex's Dr. Bernard Sherman "Conceived" It

Merck scientists invented the pharmaceutical compound enalapril for the treatment of high blood pressure, and developed a process for making enalapril tablets in the early 1980s.[3] Merck began using the manufacturing process at least as early as 1983, and sold enalapril tablets made by this process since 1986 under the trademark VASOTEC® in the United States.[4]

Merck publicly disclosed the ingredients used in its VASOTEC® tablet process in at least two publications: the 1988 edition of the French pharmaceutical reference publication *Dictionnaire Vidal*, and the 1992 Canadian product circular for VASOTEC® tablets.[5]

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[3] *Apotex USA, Inc. v. Merck & Co., Inc.*, 254 F.3d 1031, 1034 (Fed. Cir. 2001).

[4] *Id.*

[5] *Id.*

Merck then publicly disclosed how to mix the ingredients. Merck and its Canadian affiliate Merck Frosst Canada, Inc. sued Apotex's Canadian affiliate Apotex, Inc. in Canada for infringing Merck's Canadian patent that covered enalapril.[6] During the Canadian litigation, Merck's VASOTEC® tablet process was the subject of public testimony. On March 28, 1994, Mr. Brian McLeod, then Vice-President of Marketing for Merck Frosst, presented a tutorial accompanied by a videotape in open court that disclosed how Merck mixed the ingredients in its VASOTEC® tablet process.[7]

Thus, as of March 28, 1994, Merck had publicly disclosed the ingredients used in its VASOTEC® tablet process (the 1988 *Dictionnaire Vidal* and the 1992 Canadian product circular) and how to mix them (McLeod's testimony).[8] By that time, Merck's VASOTEC® tablets made by this process had also been available to patients for about eight years.

But on August 4, 1995, Apotex filed a United States patent application naming Apotex's President and CEO Dr. Bernard Sherman as the inventor of a process using ingredients and methods identical to those publicly described by Merck. Apotex eventually obtained two United States patents. Apotex asserted both patents against Merck in the United States District Court for the Northern District of Illinois ("*Apotex I*").

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[6] *Id.*

[7] *Id.*

[8] *Id.*

In *Apotex I*, Apotex admitted that Sherman "conceived" the invention claimed by the Apotex patents no earlier than March 30, 1994 (*i.e.*, two days after McLeod's public testimony at the Canadian Apotex trial).

The district court in *Apotex I* held on summary judgment that Merck's public disclosures invalidated Apotex's patents.[9] Apotex's patents were invalid under 35 U.S.C. § 102(g), which provides that "[a] person shall be entitled to a patent unless . . . (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed or concealed it." A unanimous panel of the Federal Circuit affirmed, even while presuming that Merck initially maintained its VASOTEC® tablet process as a trade secret:

> Thus, even though **Merck may have suppressed or concealed the process** for a period of time after it reduced it to practice in 1983, as long as it "resumed activity" (*i.e.*, made the benefits of its invention known to the public) before Apotex's entry into the field, it cannot be deemed to have suppressed or concealed the invention within the meaning of § 102(g).
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> **Merck made several disclosures following its period of suppression or concealment**

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[9] *Apotex Corp. v. Merck & Co., Inc.*, 2000 WL 97582 (N.D.Ill. 2000). The district court also denied Apotex's motion for reconsideration. *Apotex Corp. v. Merck & Co., Inc.*, 2000 WL 656670 (N.D.Ill. 2000).

> **that made the invention publicly known, all of which took place before Apotex's entry into the field (here, Dr. Sherman's alleged conception in April of 1994).** First, Merck disclosed the ingredients used in manufacturing VASOTEC® tablets in the 1988 edition of the Dictionnaire Vidal. It also widely distributed the product monograph in Canada from October 1992 through 1994, which similarly disclosed the ingredients it used in its manufacturing process. Merck also provided a step-by-step description of the process through the testimony given by Brian McLeod at the Canadian trial on March 28, 1994.

Apotex USA, Inc. v. Merck & Co., Inc., 254 F.3d 1031, 1040 (Fed. Cir. 2001) (emphasis added). The Federal Circuit rejected Apotex's petition for rehearing and rehearing *en banc*. Finally, this Court denied Apotex's petition for writ of *certiorari*.[10]

B. Absent Evidence of Fraud, Apotex Has Focused Upon Relitigating *Apotex I*

In May 2004, former Merck scientist Dr. Gerald Brenner testified as an expert witness at a trial for a case in which the Warner-Lambert Company sued Teva Pharmaceuticals USA, Inc. for infringement of a Warner-Lambert patent related to quinapril, a medicinal

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[10] *Apotex USA, Inc. v. Merck & Co., Inc.*, 534 U.S. 1172 (2002).

compound similar to enalapril.[11] Dr. Brenner testified about additional details of Merck's optimized VASOTEC® tablet process, including parameters that were neither disclosed nor claimed by the invalid Apotex patents (and therefore, not at issue in *Apotex I*). Apotex obtained full discovery about these additional parameters in *Apotex I*. Dr. Brenner also testified that Merck might have maintained aspects of its optimized VASOTEC® tablet process as a trade secret, albeit well before Merck had publicly disclosed the ingredients and how to mix them.

Nevertheless, based upon nothing but Brenner's testimony during the *Warner-Lambert* case, Apotex filed the current case ("*Apotex II*") against Merck, seeking relief under Rule 60(b) to have the *Apotex I* judgment set aside based upon alleged fraud. But in *Apotex II*, Apotex has not presented any evidence that Merck and its attorneys did anything improper in *Apotex I*. Accordingly, the district court once again granted summary judgment in favor of Merck. The district court considered Dr. Brenner's testimony during the *Warner-Lambert* case and determined "Apotex has not offered any evidence – much less clear and convincing evidence – from which a fact finder could determine that Merck suppressed its process (*i.e.*, the process patented by Apotex) after March 28, 1994."[12] The district court also

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[11] *See Warner-Lambert Company v. Teva Pharmaceuticals USA, Inc.*, 2004 WL 1498162 (D.N.J. 2004); 418 F.3d 1326 (Fed. Cir. 2005).

[12] *Apotex Corp. v. Merck & Co., Inc.*, 2006 WL 1155954, fn. 1 (N.D.Ill. 2006).

observed "Apotex has not offered evidence that Merck deliberately withheld or fabricated evidence [*e.g.*, the public disclosures of the *Dictionnaire Vidal*, the Canadian product circular, or McLeod's Canadian demonstration] in the previous litigation."[13]

Again, a unanimous panel of the Federal Circuit affirmed under the abuse of discretion standard of review that applies to Rule 60(b) actions. As the Federal Circuit explained when it reviewed Dr. Brenner's testimony from the *Warner-Lambert* case, "Merck's processing details, which are not asserted to be invented by Apotex, did not warrant detailed disclosure, and that the presentation of the Merck process did not establish fraud on the court."[14] Dr. Brenner's testimony during the *Warner-Lambert* case did not establish fraud, and "the district court's finding [in *Apotex II*] that it [the patent process] was not abandoned, suppressed or concealed [under 35 U.S.C. § 102(g)] was not shown to be in error."[15] Indeed, the Federal Circuit held that Apotex had not even made a *prima facie* case of fraud.[16]

The indisputable fact that Apotex presented no evidence of fraud makes this case quite clear. Apotex's

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[13] *Apotex Corp. v. Merck & Co., Inc.*, 2006 WL 1155954, *7 (N.D.Ill. 2006).

[14] *Apotex Corp. v. Merck & Co., Inc.*, 507 F.3d 1357, 1362 (Fed. Cir. 2007).

[15] 507 F.3d at 1361.

[16] 507 F.3d at 1362.

Petition presents no compelling reasons for its grant, and is nothing more than a desperate attempt for Apotex to establish the validity of its patents.

III. SUMMARY OF THE ARGUMENT

Merck respectfully urges this Court to deny Apotex's Petition, which is premised upon nothing more than its disagreement with the Federal Circuit's review of the district court's judgment in *Apotex II* for abuse of discretion. Apotex wrongly argues that there is a "split" among the circuits on the standard of review for actions under Rule 60(b), yet the only evidence Apotex presents of this "split" is its misapplication of a Third Circuit opinion. The Federal Circuit's review for abuse of discretion was correct.

Regardless, the Federal Circuit would also have been compelled to affirm under the *de novo* standard of review. The district court found that Apotex offered no evidence that Merck and its attorneys did anything improper in *Apotex I*. The Federal Circuit would also have affirmed under the *de novo* standard because no evidence of fraud exists.

IV. ARGUMENT

A. There is No "Circuit Split" on the Standard of Review for Rule 60(b) Actions

An independent action seeks equitable relief from a previous judgment under Rule 60(b), and is granted only for injustices that are deemed sufficiently gross to demand a departure from rigid adherence to the

doctrine of *res judicata*. *United States v. Beggerly*, 524 U.S. 38, 46 (1998). Relief "should be available only to prevent a grave miscarriage of justice." *Id.*

This Court has held that appellate review of a district court's denial of equitable relief occurs under the abuse of discretion standard. *Brotherhood of Locomotive Engineers v. Missouri-Kansas-Texas RR Co.*, 363 U.S. 528 (1960). And a Rule 60(b) action seeks equitable relief from a previous judgment. Accordingly, the Federal Circuit properly reviewed the district court's denial of Apotex's Rule 60(b) independent action under the abuse of discretion standard that applies to such actions seeking equitable relief.

The Seventh Circuit has consistently held that review of a district court's denial of relief under Rule 60(b) occurs under the abuse of discretion standard.[17]

> The general rule in this circuit is that relief from a judgment under rule 60(b) is an extraordinary remedy granted only in exceptional circumstances. The decision to grant relief under rule 60(b) is left to the sound discretion of the trial court, and review of a trial court's decision to grant or deny rule 60(b) relief is subject to an abuse of discretion standard.

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[17] The Rule 60(b) analysis, even in a patent case like this, is resolved according to regional circuit law. *See Schreiber Foods, Inc. v. Beatrice Cheese, Inc.*, 402 F.3d 1198, 1204-05 (Fed. Cir. 2005).

United States v. Zima, 766 F.2d 1153, 1156 (7th Cir. 1985). *See also C.K.S. Engineers, Inc.*, 726 F.2d 1202, 1204-05 (7th Cir. 1984); *Brickwood Contractors, Inc. v. U.S.*, 288 F.3d 1371, 1376 (Fed. Cir. 2002). This deferential standard of review is appropriate given that "relief from a judgment under rule 60(b) is an extraordinary remedy and is granted only in exceptional circumstances." 766 F.2d at 1157.

As even Apotex admits, the Second, Sixth, Ninth, Eleventh, and Federal Circuits all hold that review of Rule 60(b) actions occurs under the abuse of discretion standard.[18] But Apotex then attempts to concoct a "circuit split" through misapplication of the Third Circuit's opinion in *Herring v. United States*, 424 F.3d 384 (3rd Cir. 2005). In *Herring*, the plaintiff alleged that the United States had committed fraud in an earlier litigation, and sought to have the judgment from the earlier litigation set aside through a Rule 60(b) independent action. The case ended when the district court granted the Government's Fed. R. Civ. P. 12(b)(6) motion to dismiss because the plaintiff had not alleged sufficient facts to meet the rigorous standards of Rule 60(b). On appeal, the Third Circuit reviewed under the *de novo* standard that applies to review of Fed. R. Civ. P. 12(b)(6) motions to dismiss.[19] Of course, if the Third

[18] Petition at 12-13.

[19] 424 F.3d at 389 ("Under the normal *de novo* review that applies to a district court's grant of a Rule 12(b)(6) motion to dismiss for failure to state a claim, we can determine whether the Appellants have alleged facts which, if true, provide a basis for relief under the very demanding legal standard for fraud upon the court.")

Circuit in *Herring* were instead reviewing the district court's disposition of the Rule 60(b) allegations on the merits (*i.e.*, disposition on the merits of an action seeking equitable relief), the Third Circuit would have instead reviewed under the abuse of discretion standard. *See Brotherhood of Locomotive Engineers v. Missouri-Kansas-Texas RR Co.*, 363 U.S. 528 (1960) (district court denial of equitable relief is reviewed for abuse of discretion).

Apotex's argument for a *de novo* standard of review would create an absurd result. Rule 60(b) motions, which must be brought within one year of judgment, are reviewed under the abuse of discretion standard. Yet in Apotex's view, Rule 60(b) independent actions, which seek the same type of relief as Rule 60(b) motions[20] and are brought one year after judgment, should instead be reviewed under the *de novo* standard. It should not be easier to seek Rule 60(b) relief a year after entry of judgment through an independent action, than it would be through a motion brought within a year after judgment. If Apotex were correct, it would become easier to strike down a judgment as time progressed, contrary to the principle of finality of judgment.[21]

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[20] *See Landau & Cleary, Ltd. v. Hribar Trucking, Inc.*, 867 F.2d 996, 1000 (7th Cir. 1989)("In other words, a proper 'independent action' must seek the same type of relief one seeks under Rule 60(b).")

[21] Rule 60(b) relief is granted only for injustices that are deemed sufficiently gross to demand a departure from rigid adherence to the doctrine of *res judicata*. *United States v. Beggerly*, 524 U.S. 38, 46 (1998).

B. The Federal Circuit Would Have Also Affirmed Under the *De Novo* Standard

Apparently, Apotex believes that under the less deferential *de novo* standard of review, the Federal Circuit would have reversed the district court's rejection of Apotex's Rule 60(b) independent action. Again, Apotex is wrong. Because there is no evidence of fraud, the Federal Circuit would have also been compelled to affirm under the *de novo* standard.

The district court and the Federal Circuit made it quite clear that there is no evidence that Merck and its attorneys had done anything improper in *Apotex I*. As the district court explained in its *Apotex II* opinion:

> Apotex has not offered any evidence – much less clear and convincing evidence – from which a fact finder could determine that Merck suppressed its process (*i.e.*, the process patented by Apotex) after March 28, 1994.[22]
>
> * * * * *
>
> Apotex has not offered evidence that Merck deliberately withheld or fabricated evidence [e.g., the public disclosures of the Dictionnaire Vidal, the Canadian product circular, or McLeod's Canadian demonstration] in the previous litigation.[23]

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[22] *Apotex Corp. v. Merck & Co., Inc.*, 2006 WL 1155954, fn. 1 (N.D.Ill. 2006).

[23] *Apotex Corp. v. Merck & Co., Inc.*, 2006 WL 1155954, *7 (N.D.Ill. 2006).

And in the Federal Circuit's affirmance, the Federal Circuit noted that Apotex could not even establish a *prima facie* case of fraud.[24]

Establishing fraud upon the court under Rule 60(b) requires "egregious . . . conduct that might be thought to corrupt the judicial process itself, as where a party bribes a judge or inserts bogus documents into the record." *Oxxford Clothes XX, Inc. v. Expediters Int'l of Washington, Inc.*, 127 F.3d 574, 578 (7th Cir. 1997). In *Apotex II*, no evidence of any fraud exists (much less, evidence of a false document or bribing a judge), and the Federal Circuit would have been compelled to affirm under any standard of review.

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[24] *Apotex Corp. v. Merck & Co., Inc.*, 507 F.3d 1357, 1362 (Fed. Cir. 2007).

V. CONCLUSION

For all these reasons, Merck respectfully requests that Apotex's Petition be DENIED.

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